UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/737,128	12/15/2003	Michael John Rutter	CHM-010	5727

38155 7590 10/04/2005

HASSE & NESBITT LLC
7550 CENTRAL PARK BLVD.,
MASON, OH 45040

EXAMINER	
PATEL, NIHIR B	
ART UNIT	**PAPER NUMBER**
3743	

DATE MAILED: 10/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/737,128	RUTTER, MICHAEL JOHN	
	Examiner	Art Unit	
	Nihir Patel	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *September 29th, 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to the Declaration

The declaration under 37 CFR 1.132 filed September 16th, 2005 is insufficient to overcome the rejection of claims **23 and 26** as set forth in the last Office action. The applicant states in the declaration **(paragraph 10)** that **"the distance from stoma site in the trachea to the carina (covered by the distal section of the tube); the distance from the inner tracha to the chest wall (covered by the intermediate section of the tube); and the distance from the stoma site at the chest wall to the oxygen source (covered by the proximal section of the tube)"** are the reference points that are used to design the claimed tube. However, the applicant's specification and claims do not provide support for the facts set forth above nor are the limitations commensurate in scope of the claims.

The applicant states in the declaration **(paragraph 12)** that **"typically a 2 year old patient requiring a tracheostomy has a distance of between about 6 cm to about 8 cm from the stoma site in the trachea to the carina (the carina being the bifurcation point of the trachea into the bronchial tree); a distance of between about 4 cm to about 6 cm from the inner trachea to the chest wall; and a distance of between about 20 cm to about 24 cm from the chest wall to the oxygen source (which would be positioned away from the patient during surgery)".** While the applicant states, "...that a **typical** 2 year old..." has the distances listed above, no support has been provided in the applicant's declaration for what constitutes a typical 2 year old and how the applicant arrived at the parameters for a typical 2 year old (i.e., what was the study group, how many girls and boys, weight, height, what factors were used by the applicant to arrive at "...a typical 2 year old..."). Also, the "...anatomical reference points to

create the claimed tube..." has not been presented in the instant application nor claims and now applicant presents such as support for the claimed invention. There is also no support in the instant application with respect to **paragraph 10** of the declaration. One or ordinary skill in the art through mere routine experimentation could arrive at the claimed length ratios, because one of ordinary skill in the art would have known that different ratios are required for different user's and in different procedures being performed (i.e., pediatric, infant, adolescent, adult, elderly, thin, obese, patients) and such users would require different ratio lengths of the sections of the tracheostomy tube in order for the tube to be used in different situations and with different users. Applicant's declaration is stating facts not commensurate with the scope of the claims (i.e., in the claims there is not mention of how the tube is to be used, as mentioned in paragraphs 12-14 of the declaration, applicant states in paragraph 15, "...the distances are important to the proper use and function but such limitations are not presented in the claims; nor the importance of such use or function has been presented in the declaration.

With respect to paragraphs 13, 14, and 16, note explanation above as the remarks by Applicant are basically the same, therefore the examiners explanation above would be the same for the paragraphs 13, 14, and 16 in Applicant's declaration.

In reference to paragraph 18 of the declaration, the applicant states **"if the ratios are not used then there is an increased likelihood for untoward events to occur.".** It is unclear as to what Applicant means by, "...untoward events to occur..." and applicant has not provided any examples of such events. One of ordinary skill in the art would know that during certain procedures (e.g. surgeries) unexpected events can occur (e.g., drop in blood pressure, which may require a transfusion, thereby making the placement of the breathing tube important so that the

OR staff can provide immediate care, while not interfering with the placement of breathing tube ensuring the patient remains ventilated) and the primary concern is the breathing tube remaining intact while allowing the OR staff to provide care to the patient. Therefore one or ordinary skill in the art could arrive at such length ratios for the distances of the tubes in order ensure the tube is placed in a position which will not be dislodged from the patient and allow OR staff to provide any care needed.

With respect to paragraph 19, of the declaration, Applicant has not provided any support except a statement, which one of ordinary skill in the art would find obvious.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Drawings

The drawings **(figures 1 and 2)** are objected to because they are not scaled. When referring to the drawings the ratio of the length of the distal section to the length of the intermediate section is not about 1.0 to about 2.0 as claimed in claims 1, 17 and 23 but rather also most the same and the ratio of the length of the proximal section to the length of the distal section is not about 2.0 to about 4.0 as claimed in claims 1, 17 and 23, when looking at the drawings it seems as if the proximal section is three times the length of the distal section. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be

removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "...the ratio of the length of the distal section to the length of the intermediate section is from about 1.0 to about 2.0 and the ratio of the length of the proximal section to the length of the distal section is from about 2.0 to anout 4.0..." must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the

renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are: tracheotomy endotracheal tube. Tracheotomy and endotracheal are two different tubes. In the art a tracheotomy is inserted into the neck area where as endotracheal tube is inserted via mouth. Therefore, it is unclear if the applicant intends to claim a tracheotomy or an enotracheal tube or if the applicant is calling a tracheotomy tube an endotracheal tube and using the term endotracheal to mean the same tube as tracheotomy tube or it may be the tubes are two separate tubes. Clarification is required. The examiner is uncertain if the applicant is claiming two distinct tubes or one tube, using two different names through the specification and the claims. Referring to the specification, in certain areas of the application the applicant states that it's a tracheotomy tube **(refer to line 3 of paragraph [0016] on page 4)** and in other areas of the specification the applicant states that it's a endotracheal tube **(refer to line 3 of paragraph [0019] on page 5)**.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 17, 23 and 26 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The units and dimensions of the distal section, intermediate section and the proximal section of the tubing are critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 17, 23 and 26 recites the limitation "the ratio of the length of the distal section to the length of the intermediate section is from about 1.0 to about 2.0 and the ratio of the length of the proximal section to the length of the distal section is from about 2.0 to about 4.0". There is insufficient antecedent basis for this limitation in the claim. The applicant has failed to provide dimension and units to the lengths described in claims 1, 17, 23 and 26.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims **1 and 3 through 7** are rejected under 35 U.S.C. 102(b) as being anticipated by Inglis et al. (US 5,386,826). **Referring to claim 1,** Inglis discloses an apparatus that comprises a short distal section of the tubing **10 (see figure 1 below)**; and intermediate section of the tubing

(see figure 1 below); a pre-formed obtuse angle bend in the tube between the distal and intermediate sections **(see figure 1 below)**; an elongated proximal section of the tubing **(see figure 1 below; the examiner would like to point out that the helical coil can be extended to therefore meet the limitations of the ratio of the length of the proximal section to the length of the distal section from about 2.0 to about 4.0)**; a pre formed abrupt bend in the tube between the intermediate and proximal sections **(see figure 1 below)**; and an inflatable cuff **11 (see figure 1 below)** integrated into the distal section of the tubing; wherein the ratio of the length of the distal section to the length of the intermediate section is from about 1.0 to about 2.0 **(see figure 1 below)**.

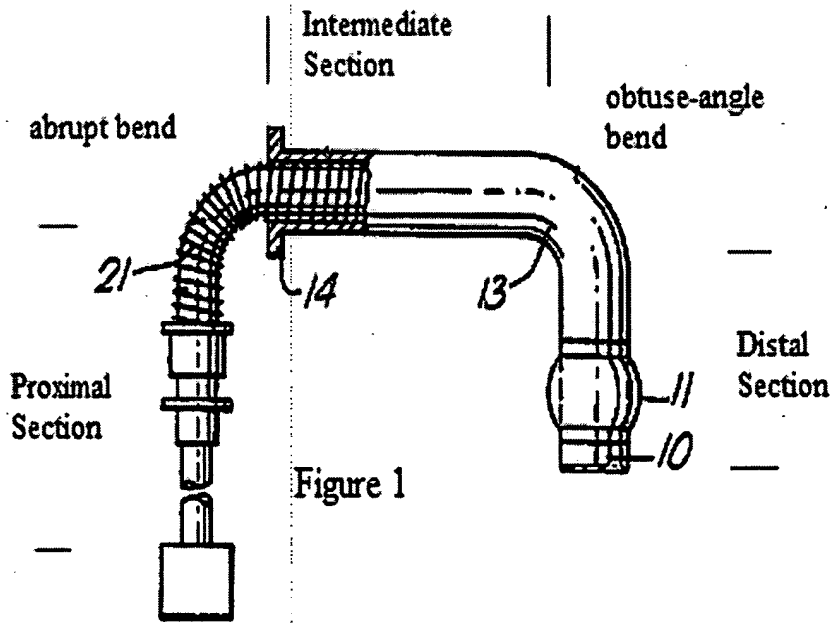


Figure 1

Referring to claim 3, Inglis discloses an apparatus wherein the abrupt ben interconnects the proximal section and the intermediate section along the length of the tube at an angle of from about 80 to about 95 degrees **(see figure 1 above).**

Referring to claim 4, Inglis discloses an apparatus wherein the abrupt bend interconnects the proximal section and the intermediate section along the length of the tube at approximately a right angle **(see figure 1 above).**

Referring to claim 5, Inglis discloses an apparatus wherein the distal section, intermediate section and the proximal section extend the same general plane **(see figure 1 above).**

Referring to claims 6 and 7, Inglis discloses an apparatus wherein the distal section, intermediate section and the proximal section are substantially rectilinear in formation **(see figure 1 above).**

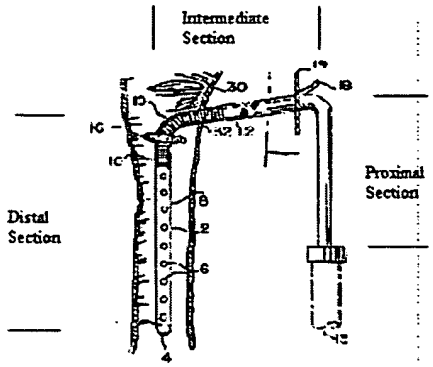
Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims **1, 3 through 11, 15, 17 and 26** are rejected under 35 U.S.C. 103(a) as being unpatentable over Beck, Jr. et al. (US 5,339,809). **Referring to claims 1, 3 through 11, 15, 17 and 26,** Beck discloses the applicant's invention as claimed with the exception of providing a tubing that comprises a ratio of the length of the distal section of the tubing to the length of the intermediate section of the tubing being about 1 to about 2/1.2 to about 1.8 and the ratio of the

length of the proximal section of the tubing to the length of the distal section of the tubing being about 2 to about 4/2.5 to about 3.5. Since Beck discloses accordion pleats 10 between the intermediate section and the distal section (see figure on the next page) it would have been obvious that the length of the distal section and the intermediate section can be adjusted to any desired ratios even to the ones claimed in claims 1, 17, 23 and 26. The examiner also reviewed the applicant's specification and discovered that the applicant has not established any criticality on why the ratio between the length of the distal section to the length of the intermediate section must be 1 to about 2/1.2 to about 1.8 and the ratio between the length of the proximal section to the length of the distal section must be 2 to about 4/2.5 to about 3.5. Since the applicant has not established any criticality the ratios are considered a simply matter of design choice and therefore it would be obvious to one in the ordinary skill of the art that through mere routine experimentation could arrive at the claimed length ratios, because one of ordinary skill in the art would have known that different ratios are required for different user's and in different procedures being performed (i.e., pediatric, infant, adolescent, adult, elderly, thin, obese, patients) and such users would require different ratio lengths of the sections of the tracheotomy tube in order for the tube to be used in different situations and with different users.



Claims **2, 12, 18, 19, 20, 23, 24, and 25** are rejected under 35 U.S.C. 103(a) as being unpatentable over Beck, Jr., et al. (US 5,339,809) in view of Nye (US 5,590,647). **Referring to claims 2, 12, 18, 19, 20, 23, 24 and 25,** Beck discloses the applicant's invention as claimed with the exception of providing a flexible tube that is made of a thermoplastic material preformed to the shape described. Nye discloses a method of providing anesthesia with a specialized tracheal tube that does provide a flexible tube that is made of a thermoplastic material preformed to the shape described. Therefore it would have been obvious to modify Beck's invention by providing a flexible tube that is made of a thermoplastic material preformed to the shape described as taught by Nye in order to make it easier for the tube to be placed in a desired position so that it will not be dislodged from the patient and allow OR staff to provide any care needed.

Claims **13, 14, 16, 21, and 22** are rejected under 35 U.S.C. 103(a) as being unpatentable over Beck, Jr., et al. (US 5,339,809) in view of Joseph (US 5,582,167). **Referring to claims 13, 14, 16, 21 and 22,** Beck discloses the applicant's invention as claimed with the exception of providing a distal section that has a beveled terminal end with at least one port opening adjacent thereto, the tube being otherwise imperforate. Joseph discloses methods and apparatus for

reducing tracheal infection using subglottic irrigation, drainage and servo-regulation of endotracheal tube cuff pressure that does provide a distal section that has a beveled terminal end with at least one port opening adjacent thereto, the tube being otherwise imperforate. Therefore it would have been obvious to modify Beck's invention by providing a distal section that has a beveled terminal end with at least one port opening adjacent thereto, the tube being otherwise imperforate as taught by Joseph in order to make it easier to deliver oxygen or any other medication.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Nihir Patel whose telephone number is (571) 272-4803. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:30 pm. If attempts to reach the examiner by telephone are unsuccessful the examiner supervisor Henry Bennett can be reached at (571) 272 4791.

NP
September 29th, 2005

Henry Bennett
Supervisory Patent Examiner
Group 3700